

Appln. No. 09/241,595  
Amd. dated April 18, 2005  
Reply to Office Action of November 17, 2004

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 4-10, 17-19, 22-27, 29-33 and 35 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The face-to-face interview on April 8, 2005, between Examiner Wehbe and Roger Browdy, representing applicants, is hereby gratefully acknowledged. In this interview, the Neurath prior art reference was discussed with applicants' representative arguing that Neurath does not teach subjects in need of CTL response stimulation and enhancement. The examiner disagreed and responded by stating that one of the biological materials mentioned by Neurath is HIV antigen and that patients infected with HIV would qualify as needing a CTL response. The examiner further stated that because Neurath teaches administering HBsAg to HIV infected subjects, Neurath is considered to anticipate the claims. Applicants' representative also proposed amendments to claim 27 to resolve the indefiniteness issue and to claim 8 to specify that three materials, the biologically active molecule, the immunostimulating molecule, and the HBsAg particle are present (support is found on page 3, lines 12-14 and 27-29 of the specification), were discussed. The examiner indicated that the

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proposed amendment to claim 27 would appear to make claims 27, 29 and 30 allowable and that she will reconsider whether or not the proposed amendment to claim 8 would place it in condition for allowance.

Claims 27 and 29-30 are newly rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the amendment to claim 27 to recite "at a temperature of about 35°C to about 60°C".

Claims 1, 4-11, 14-19, 22-26 and 31-35 are newly rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,039,522 (Neurath et al.) as evidenced by Schirmbeck et al., *Intervirology* 39(1):111-119 (1996). This rejection is respectfully traversed.

The 102(b) anticipation rejection of claims 27, 29 and 30 over Neurath was withdrawn by the examiner in view of the amendment to claim 27 which added the limitation that the particle and the biologically active molecule are incubated together at a temperature of about 35°C to about 60°C. This feature is also now added to claim 1, thereby obviating the rejection as it relates to claim 1 and claims 4-10 dependent therefrom.

Claims 11 and 14-16 are now cancelled without prejudice. Composition claims 17-19, 22-26 and 35 as well as claim 8 positively recite for the presence of three materials,

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the HBsAg particle, the biologically active material and the immunostimulating molecule. Applicants believe that the feature of entrapping two materials (the biologically active molecule along with the immunostimulating molecule as adjuvant) in a third material (the HBsAg particle) is not disclosed or taught in Neurath.


Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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